

REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Status of the claims

Claims 1-23 were pending in the subject application. Among these, the examiner had withdrawn claims 22 and 23 from consideration.

With this submission, claims 1, 3-5, 8, 11-13, 16-18, and 21-23 are amended, claim 15 is deleted, and no claims are added. Upon entry of this paper, claims 1-14 and 16-23 will be pending, with claims 1-14 and 16-21 under active consideration.

Claim rejections under 35 U.S.C. § 112

Claims 15-18 and 21 stand rejected for alleged lack of enabling and written-description support. The examiner's reasons for these rejections are detailed in the office action at items No. 6 and No. 7, respectively.

Applicants would emphasize, however, that their specification expressly relates "antibody" to a category that includes "a monoclonal antibody, a polyclonal antibody, a multi-specific antibody, and an antibody fragment [that] ... retains desired biological activity" (page 12, second paragraph 2). Informed by applicants' teachings, the skilled person could readily conceptualize and utilize these category members, each of which is well-known to the field. Thus, the skilled person would have full access to "monoclonal antibodies," understood to "comprise a heavy chain and/or a light chain having an amino acid sequence derived from each amino acid sequence of a heavy chain and/or a light chain composing an antibody by deletion, substitution, or addition of 1 or several amino acids" (*id.* at page 13, 1st paragraph; citations omitted).

In light of the foregoing, applicants respectfully demur to the rationale underlying this rejection. Solely in the interest of advancing prosecution, however, they also have canceled claim 15, without prejudice or disclaimer, thereby mooting the rejection.

Claim rejections under 35 U.S.C. § 102

Claims 1-15, 18, and 21 stand rejected for alleged anticipation by U.S. Patent No. 6,171,586 (“the ‘586 patent”). The present claims are directed to the use of glutamate buffer, however, while the ‘586 patent, as the examiner acknowledges, does *not* teach the use of glutamate buffers. Office action at item No. 11. Since an anticipating reference must teach each and every salient recitation of the affected claim, the ‘586 patent must fail as such a reference in this context. Withdrawal of the subject rejection is respectfully requested, therefore.

Claim objections under 35 U.S.C. § 103

Claims 1-15 and 17-21 stand rejected over the ‘586 patent in view of U.S. Patent No. 5,667,165 (“the ‘165 patent”). The examiner opines that, because the ‘165 patent discloses the use of glutamate buffers to minimize pH changes to a solution, one of ordinary skill in the art would have been motivated to combine its teachings with those of the ‘586 patent, with a reasonable expectation of success in doing so. Office action at item no. 11.

The examiner advances no rationale for these assertions. Moreover, the ‘165 patent does not teach the necessary use of glutamate buffers *per se*. Rather, the reference teaches the use of “most any physiological buffer,” preferring “titrate [*sic*: “citrate”], phosphate, succinate, and glutamate buffers or mixtures thereof.” Column 7, lines 44-46. “Most preferred,” in fact, is citrate buffer. *Id.* Each of these buffers may minimize pH changes, and so, in view of this generalization, no one buffer is more desirable than the next.

It is apparent, therefore, that the skilled artisan would have had to confront selecting a buffer from a virtually infinite number of combinations implicated by the ‘165 patent. Indeed, the ‘165 patent does not limit in any way the universe of mixtures of the disclosed buffers; nor are their concentrations or pH ranges constrained.

By contrast, applicants' disclosure teaches the "preferential" use of glutamic acid. See specification at page 24, 3rd paragraph (stating "most preferably, glutamic acid is used as a buffer agent"). No reasonable permutation of teachings gleaned from the cited references could have provided such guidance.

On the present record, applicants submit, the skilled artisan would have had no reason or incentive to select a glutamate buffer having a pH between 4.0 and 6.0, as presently recited, from among the myriad of alternatives proffered by the prior art. The burden remains with the examiner, therefore, to show how "one of ordinary skill in the art would have been motivated to select the claimed species or subgenus." MPEP § 2144.08(II)(4). Thus, applicants respectfully request reconsideration and withdrawal of this rejection.

Claim 16 is separately rejected over the '586 patent in view of the '165 patent and U.S. Patent No. 6,416,958 ("the '958 patent"). The '958 patent is invoked for its disclosure of a therapeutic composition comprising a HLA-DR antibody. Office action, item No. 12.

Yet, even were the '958 patent so read, *arguendo*, it still would fail to cure the above-noted deficiencies of the '586 and '165 patents. That is, no reference nor any combination of them suggests the *selection*, from a very large number of possible buffers, of a glutamate buffer having a pH between 4.0 and 6.0. Accordingly, applicants respectfully submit that claim 16 is non-obvious over this combination of references.

CONCLUSION

Applicants submit that this application is in condition for allowance, and they request an early indication to this effect. Examiner Kim is invited to contact the undersigned directly, should he feel that any issue warrants further consideration.

The Commissioner is hereby authorized to charge any additional fees, which may be required under 37 C.F.R. §§ 1.16-1.17, and to credit any overpayment to Deposit Account No. 19-0741. Should no proper payment accompany this response, then the Commissioner is authorized to charge the unpaid amount to the same deposit account. If any extension is needed for timely acceptance of submitted papers, applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorize payment of the relevant fee(s) from the deposit account.

Respectfully submitted,

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